considered to be 100 percent juice and shall be declared as “100 percent juice.”

(j) Calculations of the percentage of juice in a juice blend or a diluted juice product made directly from expressed juice (i.e., not from concentrate) shall be based on the percentage of the expressed juice in the product computed on a volume/volume basis.

(k) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then that juice to which such a major modification has been made shall not be included in the total percentage juice declaration.

(l) A beverage required to bear a percentage juice declaration on its label, that contains less than 100 percent juice, shall not bear any other percentage declaration that describes the juice content of the beverage in its label or in its labeling (e.g., “100 percent natural” or “100 percent pure”). However, the label or labeling may bear percentage statements clearly unrelated to juice content (e.g., “provides 100 percent of U.S. RDA of vitamin C”).

(m) Products purporting to be beverages that contain fruit or vegetable juices are exempted from the provisions of this section until May 8, 1994. All products that are labeled on or after that date shall comply with this section.


Subpart C—Specific Nutrition Labeling Requirements and Guidelines

SOURCE: 55 FR 60890, Nov. 27, 1991, unless otherwise noted.

§ 101.36 Nutrition labeling of dietary supplements.

(a) The label of a dietary supplement that is offered for sale shall bear nutrition labeling in accordance with this regulation unless an exemption is provided for the product in paragraph (b) of this section.

(b) The declaration of nutrition information on the label and in labeling shall contain the following information, using the subheadings and the format specified in paragraph (e) of this section.

(1) **Serving size.** (i) The subheading “Serving Size” shall be placed under the heading “Supplement Facts” and aligned on the left side of the nutrition label. The serving size shall be determined in accordance with §§101.9(b) and 101.12(b), Table 2. Serving size for dietary supplements shall be expressed using a term that is appropriate for the form of the supplement, such as “tablets,” “capsules,” “packets,” or “teaspoonfuls.”

(ii) The subheading “Servings Per Container” shall be placed under the subheading “Serving Size” and aligned on the left side of the nutrition label, except that this information need not be provided when it is stated in the net quantity of contents declaration.

(2) **Information on dietary ingredients that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) as established in §101.9(c) and their subcomponents (hereinafter referred to as “(b)(2)-dietary ingredients”).* (i) The (b)(2)-dietary ingredients to be declared, that is, total calories, calories from fat, total fat, saturated fat, trans fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron, shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with §101.9(c). Calories from saturated fat and polyunsaturated fat, monounsaturated fat, soluble fiber, insoluble fiber, sugar alcohol, and other carbohydrate may be declared, but they shall be declared when they are present in a dietary supplement in quantitative amounts by weight that exceed the amount that can be declared as zero in nutrition labeling of foods in accordance with §101.9(c).

(ii) Any other vitamins or minerals listed in §101.9(c)(9)(iv) or (c)(9) may be declared, but they shall be declared when they are added to the product for purposes of supplementation, or when a claim is made about them. Any other vitamins or minerals not present, or that are present in amounts that can be declared as zero in §101.9(c), shall not be declared (e.g., amounts corresponding
to less than 2 percent of the RDI for vitamins and minerals). Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain only individual amino acids.

(A) The names and the quantitative amounts by weight of each (b)(2)-dietary ingredient shall be presented under the heading “Amount Per Serving.” When the quantitative amounts by weight are presented in a separate column, the heading may be centered over a column of quantitative amounts, described by paragraph (b)(2)(ii) of this section, if space permits. A heading consistent with the declaration of the serving size, such as “Each Tablet Contains,” or “Amount Per 2 Tablets” may be used in place of the heading “Amount Per Serving.” Other appropriate terms, such as capsule, packet, or teaspoonful, also may be used in place of the term “Serving.”

(B) The names of dietary ingredients that are declared under paragraph (b)(2)(i) of this section shall be presented in a column aligned on the left side of the nutrition label in the order and manner of indentation specified in §101.9(c), except that calcium and iron shall follow pantothenic acid, and sodium and potassium shall follow chloride. This results in the following order for vitamins and minerals: Vitamin A, vitamin C, vitamin D, vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B_6_, folate, vitamin B_12_, biotin, pantothenic acid, calcium, iron, phosphorus, iodine, magnesium, zinc, selenium, copper, manganese, chromium, molybdenum, chloride, sodium, and potassium. The (b)(2)-dietary ingredients shall be listed according to the nomenclature specified in §101.9 or in paragraph (b)(2)(i)(B)(2) of this section.

(ii) The number of calories, if declared, and the quantitative amount by weight per serving of each dietary ingredient required to be listed under paragraph (b)(2)(i) of this section shall be presented either in a separate column aligned to the right of the column of names or immediately following the listing of names within the same column. The quantitative amounts by weight shall represent the weight of the dietary ingredient rather than the weight of the source of the dietary ingredient (e.g., the weight of calcium rather than that of calcium carbonate).

(A) These amounts shall be expressed in the increments specified in §101.9(c)(1) through (c)(7), which includes increments for sodium and potassium.

(B) The amounts of vitamins and minerals, excluding sodium and potassium, shall be the amount of the vitamin or mineral included in one serving of the product, using the units of measurement and the levels of significance given in §101.9(c)(8)(iv), except that zeros following decimal points may be dropped, and additional levels of significance may be used when the number of decimal places indicated is not sufficient to express lower amounts (e.g., the RDI for zinc is given in whole milligrams (mg), but the quantitative...
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amount may be declared in tenths of a mg).

(iii) The percent of the Daily Value of all dietary ingredients declared under paragraph (b)(2)(i) of this section shall be listed, except that the percent for protein may be omitted as provided in §101.9(c)(7); no percent shall be given for subcomponents for which DRV’s have not been established (e.g., sugars); and, for labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less than 4 years of age, or pregnant or lactating women, no percent shall be given for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium.

(A) When information on the percent of Daily Values is listed, this information shall be presented in one column aligned under the heading of “% Daily Value” and to the right of the column of amounts. The headings “% Daily Value (DV),” “% DV,” “Percent Daily Value,” or “Percent DV” may be substituted for “% Daily Value.” The heading “% Daily Value” shall be placed on the same line as the heading “Amount Per Serving.” When the acronym “DV” is unexplained in the heading and a footnote is required under (b)(2)(iii)(D), (b)(2)(iii)(F), or (b)(3)(iv) of this section, the footnote shall explain the acronym (e.g. “Daily Value (DV) not established”).

(B) The percent of Daily Value shall be calculated by dividing the quantitative amount by weight of each (b)(2)-dietary ingredient by the RDI as established in §101.9(c)(8)(iv) or the DRV as established in §101.9(c)(9) for the specified dietary ingredient and multiplying by 100, except that the percent of Daily Value for protein, when present, shall be calculated as specified in §101.9(c)(7)(i)(l). The quantitative amount by weight of each dietary ingredient in this calculation shall be the unrounded amount, except that for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber, the quantitative amount by weight declared on the label (i.e., rounded amount) may be used. The numerical value shall be followed by the symbol for percent (i.e., %).

(C) The percentages based on RDI’s and on DRV’s shall be expressed to the nearest whole percent, except that for dietary ingredients for which DRV’s have been established, “Less than 1%” or “<1%” shall be used to declare the “% Daily Value” when the quantitative amount of the dietary ingredient by weight is great enough to require that the dietary ingredient be listed, but the amount is so small that the “% Daily Value” when rounded to the nearest percent is zero (e.g., a product that contains 1 gram of total carbohydrate would list the percent Daily Value as “Less than 1%” or “<1%”).

(D) If the percent of Daily Value is declared for total fat, saturated fat, total carbohydrate, dietary fiber, or protein, a symbol shall follow the value listed for those nutrients that refers to the same symbol that is placed at the bottom of the nutrition label, below the bar required under paragraph (e)(6) of this section and inside the box, that is followed by the statement “Percent Daily Values are based on a 2,000 calorie diet.”

(E) The percent of Daily Value shall be based on RDI and DRV values for adults and children 4 or more years of age, unless the product is represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women, in which case the column heading shall clearly state the intended group. If the product is for persons within more than one group, the percent of Daily Value for each group shall be presented in separate columns as shown in paragraph (e)(10)(ii) of this section.

(F) For declared subcomponents that have no DRV’s and, on the labels of dietary supplements of vitamins and minerals that are represented or purported to be for use by infants, children less that 4 years of age, or pregnant or lactating women, for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium, a symbol (e.g., an asterisk) shall be placed in the “Percent Daily Value” column that shall refer to the same symbol that is placed at the bottom of the nutrition label, below the last
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heavy bar and inside the box, and fol-
lowed by the statement “Daily Value
not established.”

(G) When calories, calories from fat, or calories from saturated fat are de-
clared, the space under the “% Daily
Value” column shall be left blank for
these items. When there are no other
(b)(2)-dietary ingredients listed for
which a value must be declared in the
“% Daily Value” column, the column
may be omitted as shown in paragraph
(e)(10)(vii) of this section. When the “% Daily
Value” column is not required, but the dietary ingredients listed are
subject to paragraph (b)(2)(iii)(F) of
this section, the symbol required in
that paragraph shall immediately fol-
low the quantitative amount by weight
for each dietary ingredient listed under
“Amount Per Serving.”

(3) Information on dietary ingredients
for which RDI’s and DRV’s have not been
established.

(i) Dietary ingredients for
which FDA has not established RDI’s
or DRV’s and that are not subject to
regulation under paragraph (b)(2) of
this section (hereinafter referred to as
“other dietary ingredients”) shall be
declared by their common or usual
name when they are present in a die-
tary supplement, in a column that is
under the column of names described in
paragraph (b)(2)(i)(B) of this section or,
as long as the constituents of an other
dietary ingredient are not listed, in a
linear display, under the heavy bar de-
scribed in paragraph (e)(6) of this sec-
tion, except that if no (b)(2)-dietary in-
gredients are declared, other dietary
ingredients shall be declared directly
beneath the heading “Amount Per
Serving” described in paragraph
(b)(2)(i)(A) of this section.

(ii) The quantitative amount by
weight per serving of other dietary in-
gredients shall be presented in the
same manner as the corresponding in-
formation required in paragraph
(b)(2)(i) of this section or, when a lin-
ear display is used, shall be presented
immediately following the name of the
other dietary ingredient. The quan-
titative amount by weight shall be the
weight of the other dietary ingredient
listed and not the weight of any com-
ponent, or the source, of that dietary
ingredient.

(A) These amounts shall be expressed
using metric measures in appropriate
units (i.e., 1,000 or more units shall be
declared in the next higher set of units,
e.g., 1,100 mg shall be declared as 1.1 g).

(B) For any dietary ingredient that is
a liquid extract from which the solvent
has not been removed, the quantity
listed shall be the volume or weight of
the total extract. Information on the
condition of the starting material shall
be indicated when it is fresh and may
be indicated when it is dried. Informa-
tion may be included on the concen-
tration of the dietary ingredient and the
solvent used, e.g., “fresh dandelion
root extract, x (y:z) in 70% ethanol,”
where x is the number of milliliters
(mL) or mg of the entire extract, y is
the weight of the starting material and
z is the volume (mL) of solvent. Where
the solvent has been partially removed
(not to dryness), the final concen-
tration, when indicated, shall be stated
(e.g., if the original extract was 1:5 and
50 percent of the solvent was removed,
then the final concentration shall be
stated as 1:2.5). Where the name of the
solvent used is not included in the nu-
trition label, it is required to be listed
in the ingredient statement in accord-
ance with §101.4(g).

(C) For a dietary ingredient that is
an extract from which the solvent has
been removed, the weight of the ingre-
dient shall be the weight of the dried
extract.

(iii) The constituents of a dietary in-
gredient described in paragraph (b)(3)(i)
declared indented
below the dietary ingredient and fol-
lowed by their quantitative amounts
per serving, except that dia-
tary ingredients described in paragraph
(b)(2) of this section shall be listed in
accordance with that section. When the
constituents of a dietary ingredient de-
scribed in paragraph (b)(3)(i) of this
section are listed, all other dietary in-
gredients shall be declared in a col-
umn; however, the constituents them-
selves may be declared in a column or
in a linear display.

(iv) Other dietary ingredients shall
bear a symbol (e.g., an asterisk) in the
column under the heading of “% Daily
Value” that refers to the same symbol
placed at the bottom of the nutrition
label and followed by the statement
“Daily Value not established,” except that when the heading “% Daily Value” is not used, the symbol shall follow the quantitative amount by weight for each dietary ingredient listed.

(c) A proprietary blend of dietary ingredients shall be included in the list of dietary ingredients described in paragraph (b)(3)(i) of this section and identified by the term “Proprietary Blend” or other appropriately descriptive term or fanciful name and may be highlighted by bold type. Except as specified in this paragraph, all other requirements for the listing of dietary ingredients in dietary supplements are applicable.

(1) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(2) of this section shall be declared in accordance with paragraph (b)(2) of this section.

(2) Dietary ingredients contained in the proprietary blend that are listed under paragraph (b)(3) of this section (i.e., “other dietary ingredients”) shall be declared in descending order of predominance by weight, in a column or linear fashion, and indented under the term “Proprietary Blend” or other appropriately descriptive term or fanciful name.

(3) The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend and shall be placed on the same line to the right of the term “Proprietary Blend” or other appropriately descriptive term or fanciful name.

(d) The source ingredient that supplies a dietary ingredient may be identified within the nutrition label in parentheses immediately following or indented beneath the name of a dietary ingredient and preceded by the words “as” or “from,” e.g., “Calcium (as calcium carbonate),” except that manner of presentation is unnecessary when the name of the dietary ingredient (e.g., Oriental ginseng) or its synonym (e.g., ascorbic acid) is itself the source ingredient. When a source ingredient is identified in parentheses within the nutrition label, or when the name of the dietary ingredient or its synonym is the source ingredient, it shall not be required to be listed again in the ingredient statement that appears outside of the nutrition label. When a source ingredient is not identified within the nutrition label, it shall be listed in an ingredient statement in accordance with §101.4(g), which shall appear outside and immediately below the nutrition label or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label.

(1) Source ingredients shall be identified in accordance with §101.4 (i.e., shall be listed by common or usual name, and the listing of botanicals shall specify the part of the plant from which the ingredient is derived) regardless of whether they are listed in an ingredient statement or in the nutrition label.

(2) When source ingredients are listed within the nutrition label, and two or more are used to provide a single dietary ingredient, all of the sources shall be listed within the parentheses in descending order by weight.

(3) Representations that the source ingredient conforms to an official compendium may be included either in the nutrition label or in the ingredient list (e.g., “Calcium (as calcium carbonate USP)”).

(e) Nutrition information specified in this section shall be presented as follows:

(1) The title, “Supplement Facts,” shall be set in a type size larger than all other print size in the nutrition label and, unless impractical, shall be set full width of the nutrition label. The title and all headings shall be
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bolded to distinguish them from other information.

(2) The nutrition information shall be enclosed in a box by using hairlines.

(3) All information within the nutrition label shall utilize:

(i) A single easy-to-read type style.

(ii) All black or one color type, printed on a white or other neutral contrasting background whenever practical.

(iii) Upper- and lowercase letters, except that all uppercase lettering may be utilized for packages that have a total surface area available to bear labeling of less than 12 square inches.

(iv) At least one point leading (i.e., space between lines of text), and

(v) Letters that do not touch.

(4) Except as provided for small and intermediate-sized packages under paragraph (i)(2) of this section, information other than the title, headings, and footnotes shall be in uniform type size no smaller than 8 point. Type size no smaller than 6 point may be used for column headings (e.g., “Amount Per Serving” and “% Daily Value”) and for footnotes (e.g., “Percent Daily Values are based on a 2,000 calorie diet”).

(5) A hairline rule that is centered between the lines of text shall separate each dietary ingredient required in paragraph (b)(2) and (b)(3) of this section from the dietary ingredient above and beneath it, as shown in paragraph (e)(10) of this section.

(6) A heavy bar shall be placed:

(i) Beneath the subheading “Servings Per Container” except that if “Servings Per Container” is not required and, as a result, not declared, the bar shall be placed beneath the subheading “Serving Size.”

(ii) Beneath the last dietary ingredient to be listed under paragraph (b)(2)(i) of this section, if any, and

(iii) Beneath the last other dietary ingredient to be listed under paragraph (b)(3) of this section, if any.

(7) A light bar shall be placed beneath the headings “Amount Per Serving” and “% Daily Value.”

(8) If the product contains two or more separately packaged dietary supplements that differ from each other (e.g., the product has a packet of supplements to be taken in the morning and a different packet to be taken in the afternoon), the quantitative amounts and percent of Daily Value may be presented as specified in this paragraph in individual nutrition labels or in one aggregate nutrition label as illustrated in paragraph (e)(10)(iiii) of this section.

(9)(i) The quantitative amount by weight (or volume, if permitted) and the percent of Daily Value of each dietary ingredient may be presented on a “per unit” basis in addition to the “per serving” basis required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients. If “per unit” information is provided, it must be presented in additional columns to the right of the “per serving” information and be clearly identified by appropriate headings.

(ii) Alternatively, if a recommendation is made in other parts of the label that a dietary supplement be consumed more than once per day, the total quantitative amount by weight (or volume, if permitted) and the percent of Daily Value of each dietary ingredient may be presented on a “per day” basis in addition to the “per serving” basis required by paragraphs (b)(2)(ii) and (b)(2)(iii) of this section for (b)(2)-dietary ingredients and (b)(3)(ii) and (b)(3)(iv) of this section for other dietary ingredients. If “per day” information is provided, it must be presented in additional columns to the right of the “per serving” information and be clearly identified by appropriate headings and/or be presented in a parenthetical statement as part of the “Serving Size” declaration. A sample illustration for “per day” information in a column format is provided in paragraph (e)(11)(viii) of this section. As illustrated, the additional “Per Day” column heading is followed parenthetically by the number of servings recommended per day in other parts of the label (e.g., “Per Day (3 Capsules)”). When the parenthetical statement format following the “Serving Size” declaration is used as an alternative to the column format, the statement must provide no more than simple instructions regarding how to calculate the “per day” amount for the number of servings per day recommended in
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other parts of the label (e.g., “Serving Size: 1 Caplet (Multiply amounts by 3 for total daily amount)”)). When the parenthetical statement format following the “Serving Size” declaration is used in addition to the column format, the statement must provide no more than a simple declaration of the number of servings recommended in other parts of the label (e.g., “Serving Size: 1 Caplet (Total daily amount: 3 caplets per day)”).

(10) In the interest of uniformity of presentation, FDA urges that the information be presented using the graphic specifications set forth in appendix B to part 101, as applicable.

(11) The following sample labels are presented for the purpose of illustration:
(i) Multiple vitamins:

### Supplement Facts

| Vitamin A (as retinyl acetate and 50% as beta-carotene) | 5000 IU | 100% |
| Vitamin C (as ascorbic acid) | 80 mg | 100% |
| Vitamin D (as cholecalciferol) | 400 IU | 100% |
| Vitamin E (as d-alpha tocopherol acetate) | 30 IU | 100% |
| Thiamin (as thiamin mononitrate) | 15 mg | 100% |
| Riboflavin | 17 mg | 100% |
| Niacin (as niacinamide) | 20 mg | 100% |
| Vitamin B6 (as pyridoxine hydrochloride) | 2.0 mg | 100% |
| Folate (as folic acid) | 400 mcg | 100% |
| Vitamin B12 (as cyanocobalamin) | 8 mcg | 100% |
| Biotin | 30 mcg | 10% |
| Pantothenic Acid (as calcium pantothenate) | 10 mg | 100% |

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

(ii) Multiple vitamins for children and adults:

### Supplement Facts

| Calories | 5 |
| Total Carbohydrate | 1 g | < 1%* |
| Sugars | 1 g | < 1%* |
| Vitamin A (50% as beta-carotene) | 2500 IU | 100% |
| Vitamin C | 40 mg | 100% |
| Vitamin D | 400 IU | 100% |
| Vitamin E | 15 IU | 100% |
| Thiamin | 11 mg | 100% |
| Riboflavin | 12 mg | 100% |
| Niacin | 14 mg | 100% |
| Vitamin B6 | 1.1 mg | 100% |
| Folate | 300 mcg | 100% |
| Vitamin B12 | 5 mcg | 100% |

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Sucrose, sodium ascorbate, stearic acid, gelatin, maltodextrin, artificial flavors, d-alpha tocopheryl acetate, niacinamide, magnesium stearate, Yellow 6, artificial colors, stearic acid, palmitic acid, pyridoxine hydrochloride, thiamin mononitrate, vitamin A acetate, beta-carotene, folic acid, cholecalciferol, and cyanocobalamin.
(iii) Multiple vitamins in packets:

## Supplement Facts

**Serving Size**: 1 Packet  
**Servings Per Container**: 10

<table>
<thead>
<tr>
<th>Amount Per Serving</th>
<th>AM Packet</th>
<th>% Daily Value</th>
<th>PM Packet</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>2500 IU</td>
<td>50%</td>
<td>2500 IU</td>
<td>50%</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>60 mg</td>
<td>100%</td>
<td>60 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>400 IU</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin E</td>
<td>30 IU</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thiamin</td>
<td>1.5 mg</td>
<td>100%</td>
<td>1.5 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>1.7 mg</td>
<td>100%</td>
<td>1.7 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Niacin</td>
<td>20 mg</td>
<td>100%</td>
<td>20 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Vitamin B₆</td>
<td>2.0 mg</td>
<td>100%</td>
<td>2.0 mg</td>
<td>100%</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>200 mcg</td>
<td>50%</td>
<td>200 mcg</td>
<td>50%</td>
</tr>
<tr>
<td>Vitamin B₁₂</td>
<td>3 mcg</td>
<td>50%</td>
<td>3 mcg</td>
<td>50%</td>
</tr>
<tr>
<td>Biotin</td>
<td>5 mcg</td>
<td>50%</td>
<td>5 mcg</td>
<td>50%</td>
</tr>
</tbody>
</table>

Ingredients: Sodium ascorbate, ascorbic acid, calcium pantothenate, niacinamide, dl-alpha tocopheryl acetate, microcrystalline cellulose, artificial flavors, dextrin, starch, mono- and diglycerides, vitamin A acetate, magnesium stearate, gelatin, FD&C Blue #1, FD&C Red #3, artificial colors, thiamin mononitrate, pyridoxine hydrochloride, citric acid, lactose, sorbic acid, tricalcium phosphate, sodium benzoate, sodium caseinate, methylparaben, potassium sorbate, BHA, BHT, ergocalciferol and cyanocobalamin.
(iv) Dietary supplement containing dietary ingredient with and without RDIs and DRV's:

**Supplement Facts**

<table>
<thead>
<tr>
<th>Serving Size 1 Capsule</th>
<th>Amount Per Capsule</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Calories from Fat</td>
<td>20</td>
<td>3%*</td>
</tr>
<tr>
<td>Total Fat</td>
<td>2 g</td>
<td>3%*</td>
</tr>
<tr>
<td>Saturated Fat</td>
<td>0.5 g</td>
<td>3%*</td>
</tr>
<tr>
<td>Polyunsaturated Fat</td>
<td>1 g</td>
<td></td>
</tr>
<tr>
<td>Monounsaturated Fat</td>
<td>0.5 g</td>
<td></td>
</tr>
<tr>
<td>Vitamin A</td>
<td>4250 IU</td>
<td>85%</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>425 IU</td>
<td>106%</td>
</tr>
<tr>
<td>Omega-3 fatty acids</td>
<td>0.5 g</td>
<td></td>
</tr>
</tbody>
</table>

* Percent Daily Values are based on a 2,000 calorie diet.  
† Daily Value not established.

Ingredients: Cod liver oil, gelatin, water, and glycerin.

(v) A proprietary blend of dietary ingredients:

**Supplement Facts**

<table>
<thead>
<tr>
<th>Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)</th>
<th>Amount Per Teaspoon</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Total Carbohydrate</td>
<td>2 g</td>
<td>&lt; 1%*</td>
</tr>
<tr>
<td>Sugars</td>
<td>2 g</td>
<td></td>
</tr>
<tr>
<td>Proprietary blend</td>
<td>0.7 g</td>
<td></td>
</tr>
<tr>
<td>German Chamomile (flower)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hyssop (leaves)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Percent Daily Values are based on a 2,000 calorie diet.  
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.
(vi) Dietary supplement of an herb

![Supplement Facts]

<table>
<thead>
<tr>
<th>Serving Size 1 Capsule</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amount Per Capsule</strong></td>
</tr>
<tr>
<td>Oriental Ginseng, powdered (root)</td>
</tr>
</tbody>
</table>

* Daily Value not established.

Other ingredients: Gelatin, water, and glycerin.

(vii) Dietary supplement of amino acids:

![Supplement Facts]

<table>
<thead>
<tr>
<th>Serving Size 1 Tablet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Amount Per Tablet</strong></td>
</tr>
<tr>
<td>Calories</td>
</tr>
<tr>
<td>Isoleucine (as L-isoleucine hydrochloride)</td>
</tr>
<tr>
<td>Leucine (as L-leucine hydrochloride)</td>
</tr>
<tr>
<td>Lysine (as L-lysine hydrochloride)</td>
</tr>
<tr>
<td>Methionine (as L-methionine hydrochloride)</td>
</tr>
<tr>
<td>Cystine (as L-cystine hydrochloride)</td>
</tr>
<tr>
<td>Phenylalanine (as L-phenylalanine hydrochloride)</td>
</tr>
<tr>
<td>Tyrosine (as L-tyrosine hydrochloride)</td>
</tr>
<tr>
<td>Threonine (as L-threonine hydrochloride)</td>
</tr>
<tr>
<td>Valine (as L-valine hydrochloride)</td>
</tr>
</tbody>
</table>

* Daily Value not established.

Other ingredients: Cellulose, lactose, and magnesium stearate.
(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (e)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right must be set off by a line that distinguishes it and sets it apart from the dietary ingredients and percent of Daily Value information given to the left. The following sample label illustrates this display:

<table>
<thead>
<tr>
<th>Supplement Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serving Size 1 Caplet</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Per Caplet</th>
<th>Per Day (3 Caplets)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amount</td>
<td>% Daily Value</td>
</tr>
<tr>
<td>Calcium (as calcium citrate)</td>
<td>500 mg</td>
<td>50%</td>
</tr>
<tr>
<td>Vitamin D (as cholecalciferol)</td>
<td>125 IU</td>
<td>31%</td>
</tr>
</tbody>
</table>
(f)(1) Compliance with this section will be determined in accordance with § 101.9(g)(1) through (g)(8), except that the sample for analysis shall consist of a composite of 12 subsamples (consumer packages) or 10 percent of the

---

### Supplement Facts

**Serving Size 1 Packet**

<table>
<thead>
<tr>
<th>Amount Per Packet</th>
<th>% Daily Value</th>
<th>Amount Per Packet</th>
<th>% Daily Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (from cod liver oil)</td>
<td>5,000 IU</td>
<td>100%</td>
<td>Zinc (as zinc oxide)</td>
</tr>
<tr>
<td>Vitamin C (as ascorbic acid)</td>
<td>250 mg</td>
<td>417%</td>
<td>Selenium (as sodium selenate)</td>
</tr>
<tr>
<td>Vitamin D (as ergocalciferol)</td>
<td>400 IU</td>
<td>100%</td>
<td>Copper (as cupric oxide)</td>
</tr>
<tr>
<td>Vitamin E (as d-alpha tocopherol)</td>
<td>150 IU</td>
<td>500%</td>
<td>Manganese (as manganese sulfate)</td>
</tr>
<tr>
<td>Thiamin (as thiamin mononitrate)</td>
<td>75 mg</td>
<td>5000%</td>
<td>Chromium (as chromium chloride)</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>75 mg</td>
<td>4412%</td>
<td>Molybdenum (as sodium molybdate)</td>
</tr>
<tr>
<td>Niacin (as niacinamide)</td>
<td>75 mg</td>
<td>375%</td>
<td>Potassium (as potassium chloride)</td>
</tr>
<tr>
<td>Vitamin B₆ (as pyridoxine hydrochloride)</td>
<td>75 mg</td>
<td>3750%</td>
<td>Choline (as choline chloride)</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>400 mcg</td>
<td>100%</td>
<td>Betaine (as betaine hydrochloride)</td>
</tr>
<tr>
<td>Vitamin B₁₂ (as cyanocobalamin)</td>
<td>100 mcg</td>
<td>1667%</td>
<td>Glutamic Acid (as L-glutamic acid)</td>
</tr>
<tr>
<td>Biotin</td>
<td>100 mcg</td>
<td>33%</td>
<td>Inositol (as inositol monophosphosphate)</td>
</tr>
<tr>
<td>Pantothenic Acid (as calcium pentothenate)</td>
<td>75 mg</td>
<td>750%</td>
<td>para-Aminobenzoic acid</td>
</tr>
<tr>
<td>Calcium (from oystershell)</td>
<td>100 mg</td>
<td>10%</td>
<td>Deoxyribonucleic acid</td>
</tr>
</tbody>
</table>
| Iron (as ferrous fumarate)           | 10 mg         | 56%                                   | Boron | 500 mcg | *
| Iodine (from kelp)                   | 150 mcg       | 100%                                  |               |       |   |
| Magnesium (as magnesium oxide)       | 60 mg         | 15%                                   |               |       |   |

Other ingredients: Cellulose, stearic acid and silica.

* Daily Value not established
§ 101.36

number of packages in the same inspection lot, whichever is smaller, randomly selected to be representative of the lot. The criteria on class I and class II nutrients given in §101.9(g)(3) and (g)(4) also are applicable to other dietary ingredients described in paragraph (b)(3)(i) of this section. Reasonable excesses of these other dietary ingredients over labeled amounts are acceptable within current good manufacturing practice.

(2) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section, FDA may permit alternative means of compliance or additional exemptions to deal with the situation in accordance with §101.9(g)(9). Firms in need of such special allowances shall make their request in writing to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(g) Except as provided in paragraphs (i)(2) and (i)(5) of this section, the location of nutrition information on a label shall be in compliance with §101.2.

(h) Dietary supplements are subject to the exemptions specified as follows in:

(1) Section 101.9(j)(1) for foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age, in that nutrition labels on such foods shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol;

(2) Section 101.9(j)(13) for foods in small or intermediate-sized packages, except that:

(i) All information within the nutrition label on small-sized packages, which have a total surface area available to labeling of less than 12 square inches, shall be in type size no smaller than 4.5 point;

(ii) All information within the nutrition label on intermediate-sized packages, which have from 12 to 40 square inches of surface area available to bear labeling, shall be in type size no smaller than 6 point, except that type size no smaller than 4.5 point may be used on packages that have less than 20 square inches available for labeling and more than 8 dietary ingredients to be listed and on packages that have 20 to 40 square inches available for labeling and more than 16 dietary ingredients to be listed.

(iii) When the nutrition information is presented on any panel under §101.9(j)(13)(ii)(D), the ingredient list shall continue to be located immediately below the nutrition label, or, if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label as specified in §101.4(g).
§ 101.42 Nutrition labeling of raw fruit, vegetables, and fish.

(a) The Food and Drug Administration (FDA) urges food retailers to provide nutrition information, as provided in §101.9(c), for raw fruit, vegetables, and fish at the point-of-purchase. If retailers choose to provide such information, they should do so in a manner that conforms to the guidelines in §101.45.

(b) In §101.44, FDA has listed the 20 varieties of raw fruit, vegetables, and fish that are most frequently consumed during a year and to which the guidelines apply.

(c) FDA has also defined in §101.43, the circumstances that constitute substantial compliance by food retailers with the guidelines.

(d) By May 8, 1993, FDA will issue a report on actions taken by food retailers to provide consumers with nutrition information for raw fruit, vegetables, and fish under the guidelines established in §101.45.

(1) The report will include a determination of whether there is substantial compliance, as defined in §101.43, with the guidelines.

(2) In evaluating substantial compliance, FDA will consider only the 20 varieties of raw fruit, vegetables, and fish most frequently consumed as identified in §101.44.

(e) If FDA finds that there is substantial compliance with the guidelines for the nutrition labeling of raw fruit and vegetables or of fish, the agency will so state in the report, and the guidelines will remain in effect. FDA will reevaluate the market place for substantial compliance every 2 years.

(f) If FDA determines that there is not substantial compliance with the guidelines for raw fruit and vegetables or for raw fish, the agency will at that time issue proposed regulations requiring that any person who offers raw fruit and vegetables or fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by §101.9. Final regulations would have to be issued 6 months after issuance of proposed regulations, and they would become effective 6 months after the date of their promulgation.